


**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
03/410,539	03/24/95	WHEELER	M 7823/5

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EXAMINER	
CAMPELL, B	
ART UNIT	PAPER NUMBER
1819	17
DATE MAILED: 01/09/98	

 This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 9/16/97
- ☒ This action is FINAL
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

 A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-79 is/are pending in the application.
- Of the above, claim(s) 14, 22-77 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-13, 15-21, 78, 79 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

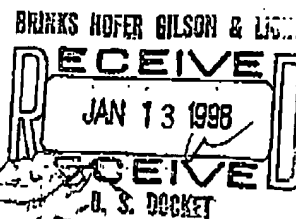
*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No. _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -



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The amendment and declaration of Matthew B. Wheeler filed September 16, 1997 have been entered. The new claims have been renumbered 78 and 79 in accordance with 37 CFR 1.126.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-21 and 79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 5,523,226, as previously stated for claims 15-21 (paper 14, p. 2). Applicant argues that the Examiner has not shown why the pending claims are obvious over the issued claims. The pending claims are obvious because passaging some cells through SCID mice is a means of testing the totipotency of the ES cells, *i.e.* a "quality control" step. Note that the ES cells resulting from the patented method are not those which have been passaged through the SCID mouse. The ES cells produced by the method of the pending claims are apparently the same as those produced by the patented method, they just have not been tested. Omitting the testing step is an obvious variation of the patented method. Applicant also argues that the rejection is inconsistent with the rejection under § 112. This argument is not persuasive because predictability is not a consideration in double patenting rejections. The primary consideration is whether a generic claim to a method of making ungulate ES cells would improperly extend the patent rights already granted for the method of making swine ES cells. Since swine are ungulates, allowance of the pending claims would result in extension of the term of the existing patent.

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Claims 1-13, 15-21, 78 and 79 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-16 and 48-50 of copending Application No. 08/473,030, as previously stated for claims 1-13 and 15-21 (paper 14, p. 2).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9-13 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to production of swine ES cells and chimeric swine, as previously stated (paper 14, p. 3).

Applicant argues that there is no legal requirement for a working example. This argument, while correct, is not persuasive because presence or absence of working examples is one of the factors to be considered when determining whether a specification is enabling (MPEP 2164.01(a)). Applicant also argues that the Examiner does not indicate what a working example would be. The Examiner does not understand how there could be any confusion on this issue. "A working example is based on work actually performed" (MPEP 2164.02).

Applicant argues that the specification provides guidance. This argument is not persuasive because there is reason to doubt that the methods which produced swine ES cell lines would be successful with any and all other ungulate species, as set forth in the previous Office action.

Applicant argues that the claimed methods have been used to produce sheep ES cells, citing the Wheeler declaration. This argument is not persuasive because the ES-like cells disclosed in the declaration do not meet an important art-accepted criterion of an ES cell, the ability to be incorporated into all cell types of an organism, particularly the germ line. For example, Nichols et al. (A47) state that "[e]mbryonic stem cells...retain the ability to participate in normal embryonic development and, following

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reintroduction to the blastocyst, they generate chimaeric animals that are mosaic in *all* their tissues. Mosaicism extends to the germ cell lineage and *ES cells can contribute fully functional gametes.*" (p. 1341, first paragraph, emphasis added). Applicant has demonstrated that the disclosed sheep ES-like cells have an appearance similar to swine ES cells, but not that they can be used to generate chimeric sheep and contribute fully functional gametes. Additional examples from the art are cited below. Kollias et al. (A37) state that "[a]fter reintroduction into blastocysts, [ES cells] can contribute to all the tissues of the mice derived from the reimplanted blastocysts, *including germ line cells*" (p. 92, emphasis added). Wurst et al. (A73) state that "ES cells resemble in many aspects ICM cells *especially in their ability to contribute to all tissues in chimeras*" (p. 33). Clark et al. (A18), discussing the isolation of putative swine ES cell lines, state that "[t]he isolation of ES cells from domestic livestock has not yet been conclusively demonstrated...[P]ig cells have been...used in blastocyst injection experiments. Preliminary results indicate...that these cells can contribute to tissues in the developing animal. *Demonstration that these cells are able to contribute to the germ line is awaited*" (p. 250, second full paragraph; emphasis added). Finally, Applicant himself has stated, "True totipotent embryonic cell types are those capable of being induced to develop into any cell type present in an entire animal" (Wheeler, col. 2, lines 61-64). Hence those skilled in the art would not accept the ES-like cells described in the declaration as "true" ES cells based solely on their appearance, particularly since true sheep ES cells have not been produced previously.

Applicant argue that the Piedrahita et al. reference is irrelevant because the authors were unable to isolate true ES cells. This argument is not persuasive. If cells of different species respond differently to identical treatments, this implies that the methods demonstrated to be effective for swine cells will need to be modified for other species.

Applicant argues that there are some similarities among the ungulates in embryonic development, and that any differences do not necessarily indicate that undue experimentation would be required to practice other embodiments of the claimed methods. These arguments are not persuasive in the absence

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of any evidence that one skilled in the art would accept Applicant's allegation that methods suitable for use with pigs could be adapted for any other ungulate species with only routine experimentation.

Applicant argues that ungulates are all in the same taxonomic genus. This is incorrect. Pigs are in the genus *Sus*, cattle in the genus *Bos*, sheep in the genus *Ovis*, horses in the genus *Equus*, etc.

The rejection is deemed proper and is maintained.

Claims 7, 8 and 78 are allowable if this application is put into condition for allowance before co-pending application 08/473,030. Should the other application mature into a patent first, action must be taken to avoid the double patenting rejection.

No claim is allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee of \$ 790 for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. If a notice of appeal and the appeal fee set forth in 37 CFR 1.17(e) were filed prior to or with the payment of the fee set forth in 37 CFR 1.17(r), the payment of the fee set forth in 37 CFR 1.17(r) by applicant will be construed as a request to dismiss the appeal and to continue prosecution under 37 CFR 1.129(a). In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

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If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Campell, whose telephone number is 703-308-4205. The examiner can normally be reached on Monday-Thursday from 8:00 to 4:30 (Eastern time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, can be reached on 703-308-2035. The FAX phone numbers for group 1800 are 703-305-4242 and 703-305-3014.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Bruce Campell

BRUCE R. CAMPELL
PRIMARY EXAMINER
GROUP 1800